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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,398	01/18/2002	Mami Ojima	2002-0041 A	2307

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WASHINGTON, DC 20006-1021

EXAMINER

POWERS, FIONA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,398

Applicant(s)

OJIMA ET AL.

Examiner

Fiona T. Powers

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 5.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Application/Control Number: 10/031,398
Art Unit: 1626

Page 2

Receipt is acknowledged of the disclosure statements filed January 18, 2002 and January 29, 2003 and the preliminary amendment filed January 18, 2002, which have been entered in the file.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 does not describe how to make a pharmaceutical composition. The term "administering" means how to give a pharmaceutical.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the

effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 to 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Tamura et al. (WO 97/37688), cited.

The reference discloses the claimed agent having angiotensin II antagonistic activity which is used for the prevention of recurrence of cerebrovascular disorder and the claimed method for the prevention of recurrence of a cerebrovascular disorder. Note paragraphs 1, 4 (cerebral apoplexy and cerebral arteriosclerosis), 8 and 9 on pages 3 to 5.

Claims 1 to 4 and 10 to 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Dowle et al. (US 5332831) or Judd et al. (WO 94/11369) or Sekine et al. (Chemical Abstracts, 127:39817, 1997) or Nagura et al. (Chemical Abstracts, 125:25882, 1996) or Stier et al. (Chemical Abstracts, 119:62704, 1993), cited.

The references disclose the claimed agent having angiotensin II antagonistic activity which is used for the prevention of recurrence of cerebrovascular disorder and the claimed method for the prevention of recurrence of a cerebrovascular disorder. Note column 1, line 1 to column 2,

Art Unit: 1626

linwe 15, column 3, line 51 to column5, line 29, column 6, lines 25 to 35 (cerebrovascular insufficiency) and column 42, lines 52 to 43, line 10 of Dowle et al.; page 1, lines 1 to 25, page 2, lines 15 to 22 (cerebrovascular insufficiency) and page 19, line 24 to page 20, line 12 of Judd et al.; and the abstracts of Sekine (cerebral apoplexy), Nagura (cerebral circulation disorder) and Stier (stroke and cerebrovascular lesions).

Claims 1 to 7 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Coniglio et al. (US 6248729), cited.

The reference discloses the claimed agent having angiotensin II antagonistic activity which is used for the prevention of recurrence of cerebrovascular disorder (cerebral infarction) and the claimed method for the prevention of recurrence of a cerebrovascular disorder. Note column 1, lines13 to 19, column3, lines 36 to 42 and claim 18.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 to 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamura et al. (WO 97/37688) and Hasegawa et al. (K. K. Nihon Rinshosha, 1993, Vol. 1, 505-508), cited by applicants.

Determination of the scope and content of the prior art (MPEP §2141.01)

Tamura et al. disclose a pharmaceutical composition containing a compound having angiotensin II antagonistic activity which is useful for the prevention of cerebrovascular disorders. Note paragraphs 1, 4 (cerebral apoplexy and cerebral arteriosclerosis), 8 and 9 on pages 3 to 5.

Hasegawa et al. describe neuropathic symptoms, dyskinesia, pathergasia, daily life action disorders and the like as aftereffects of cerebrovascular diseases.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The agent and methods disclosed by Tamura et al. differ from the claimed agent and methods in that the reference does not disclose the use of the agent for the ameliorating troubles following cerebrovascular disorder and for inhibiting progress thereof.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2413)

It would have been obvious for one of ordinary skill in the art to use the agents disclosed by Tamura et al. for the

amelioration of the aftereffects disclosed by Hasegawa et al. since it is expected that agents which prevent cerebrovascular disorders would also be useful to treat the aftereffects.

Claims 1 to 4 and 10 to 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowle et al. (US 5332831) or Judd et al. (WO 94/11369) or Sekine et al. (Chemical Abstracts, 127:39817, 1997) or Nagura et al. (Chemical Abstracts, 125:25882, 1996) or Stier et al. (Chemical Abstracts, 119:62704, 1993) and Hasegawa et al. (K. K. Nihon Rinshosha, 1993, Vol. 1, 505-508).

Determination of the scope and content of the prior art (MPEP §2141.01)

Dowle et al., Judd et al., Sekine et al., Nagura et al. and Stier et al. disclose the claimed agent having angiotensin II antagonistic activity which is used for the prevention of recurrence of cerebrovascular disorder and the claimed method for the prevention of recurrence of a cerebrovascular disorder. Note column 1, line 1 to column 2, line 15, column 3, line 51 to column 5, line 29, column 6, lines 25 to 35 (cerebrovascular insufficiency) and column 42, lines 52 to 43, line 10 of Dowle et al.; page 1, lines 1 to 25, page 2, lines 15 to 22 (cerebrovascular insufficiency) and page 19, line 24 to page 20, line 12 of Judd et al.; and the abstracts of Sekine (cerebral

apoplexy), Nagura (cerebral circulation disorder) and Stier (stroke and cerebrovascular lesions).

Hasegawa et al. describes neuropathic symptoms, dyskinesia, pathergasia, daily life action disorders and the like as aftereffects of cerebrovascular diseases.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The agent and methods disclosed by Dowle et al., Judd et al., Sekine et al., Nagura et al. and Stier et al. differ from the claimed agent and methods in that the references do not disclose the use of the agent for the ameliorating troubles following cerebrovascular disorder and for inhibiting progress thereof.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2413)

It would have been obvious for one of ordinary skill in the art to use the agents disclosed by Tamura et al. for the amelioration of the aftereffects disclosed by Hasegawa et al. since it is expected that agents which prevent cerebrovascular disorders would also be useful to treat the aftereffects.

Claims 1 to 7 and 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coniglio et al. (US 6248729).

Coniglio et al. disclose the claimed agent having angiotensin II antagonistic activity which is used for the

prevention of recurrence of cerebrovascular disorder (cerebral infarction) and the claimed method for the prevention of recurrence of a cerebrovascular disorder. Note column 1, lines 13 to 19, column 3, lines 36 to 42 and claim 18.

Hasegawa et al. describe neuropathic symptoms, dyskinesia, pathergasia, daily life action disorders and the like as aftereffects of cerebrovascular diseases.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The agent and methods disclosed by Coniglio et al. differ from the claimed agent and methods in that the reference does not disclose the use of the agent for the ameliorating troubles following cerebrovascular disorder and for inhibiting progress thereof.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2413)

It would have been obvious for one of ordinary skill in the art to use the agents disclosed by Tamura et al. for the amelioration of the aftereffects disclosed by Hasegawa et al. since it is expected that agents which prevent cerebrovascular disorders would also be useful to treat the aftereffects.

No claim is allowed.

The references made of record and not relied upon show the state of the art.

Application/Control Number: 10/031,398
Art Unit: 1626

Page 9

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 703-308-4535. The examiner can normally be reached on Monday - Friday 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 703-308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Fiona T. Powers
Fiona T. Powers
Primary Examiner
Art Unit 1626

ftp
April 21, 2003